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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/016,825 | 11/09/2001 | Harvey A. Schwertner | AFD 489 | 9046 |

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DEPARTMENT OF THE AIR FORCE

AFMC LO/JAZ

2240 B ST., RM. 100

WRIGHT-PATTERSON AFB, OH 45433-7109

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,825

Applicant(s)

SCHWERTNER ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 9 is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed on January 9, 2004 has been entered. Claims 1-8 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendments.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-4, 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwertner US Patent 5,380,667 and Kannel et al (Ann. Intern. Med. 90:85-97, 1979).

3. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

4. Applicant first argues that the meaning of "characterizing" recited in step (c) of claims 1 and 6 is directed to "marking or distinguishing" which is different in meaning from "determining." In response, Examiner states that the term "characterizing" can also be directed towards a step for "describing,"¹ the results. Any display of steps (a) and (b) is falls within such limitation.

5. Further Applicant argues that the display or characterizing step would be a "useful, concrete and tangible results" within what is contemplated in State Street. In response, Examiner states that the quoted portion of the State Street decision is directed to determination of subject matter patentability under 35 USC 101, not whether the method steps of the claim under issues was obvious over the prior art under 35

USC 103 (a). Therefore, such line of argument is moot because patentability of the subject matter was never questioned in this case.

Here, Examiner rejected the pending claims because all active process steps are taught by the cited prior art. Accordingly, the passive step (c) deemed to be an obvious modification of what has already been described in the prior art, because by performing steps (a) and (b) the risk of the CAD is already established and thus displaying the results from such steps to draw a conclusion would have been obvious for the reasons of record. The role of HDL-C and LDL-C and bilirubin is described in the prior art as predictors of the risk of CAD. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to increase the diagnostic sensitivity of Schewertner's formula by optimizing these values in the numerator and denominator of Schewertner's formula through a simple statistical experimentation wherein LDL-C is used in the numerator and the sum of HDL-C and bilirubin is used in the denominator.

Applicant's arguments that the "striking" results of the instant claims is the power and independence of the discovery is noted, but are not commensurate with the scope of the claims as the language of the claims are not directed towards comparing the strength of the instant test against what is already described in the art.

Allowable Subject Matter

Claims 5 and 9 are free of art.

¹ Attention is drawn to the meaning of the term Characterize as elaborated in Webster's II, New Riverside University Dictionary, 1994.

Claims 5,9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS



RUSSELL TRAVERS
PRIMARY EXAMINER